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(71) Applicant (for all designated States except US): MEDTRONIC, INC. (US/US); MS LC340, 710 Medtronic Parkway, Minneapolis, Minnesota 55432 (US).

(72) Inventors; and

(75) Inventors/Applicants (for US only): HO, Liem [VN/US];

865 Central Avenue, Mountain View, California 94043 (US). GOLDEN, Steve [US/US]; 618 Creek Drive, Menlo Park, California 94025 (US). SCHALLER, Laurent [CH/US]; 595 Benvenue Avenue, Los Altos, California 94024 (US).

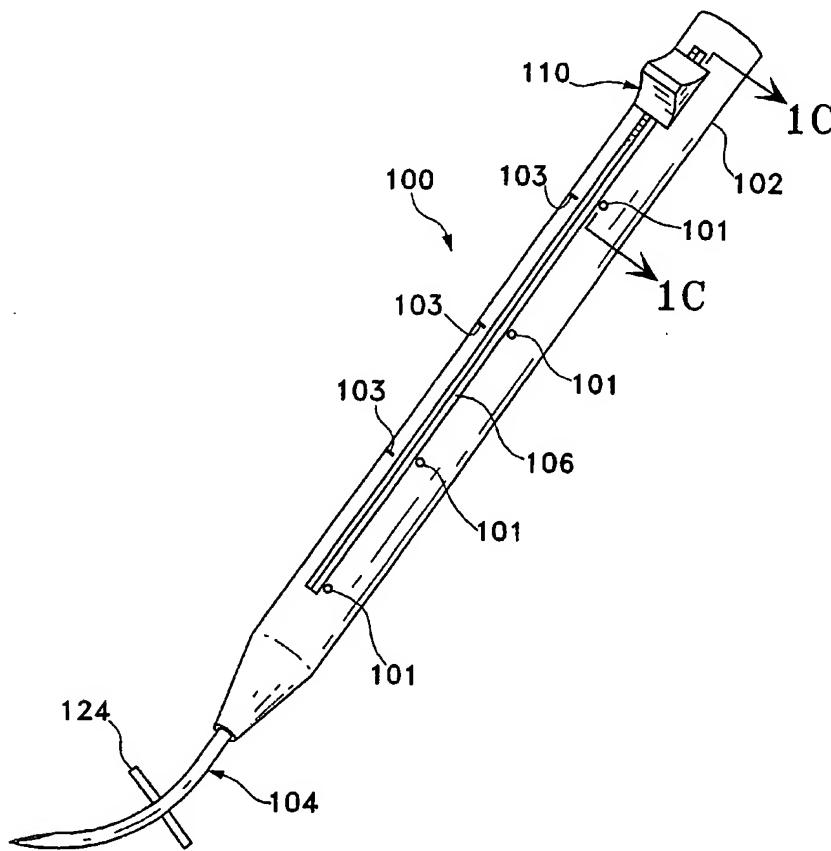
(74) Agents: HOHENSHEIL, Jeffrey, J. et al.; MS LC340, 710 Medtronic Parkway, Minneapolis, Minnesota 55432 (US).

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(54) Title: SURGICAL CONNECTION APPARATUS AND METHODS

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(57) Abstract: Surgical connection apparatus (100) comprises a support (102,104) having a proximal portion with a distal end and a proximal portion. The support forms a pathway between the proximal and distal portions. A plurality of self-closing clips (200) are slidably disposed in the pathway and a pusher is arranged to a slidably move in the pathway and push the clips in a distal direction. The apparatus facilitates partial ejection of a clip after which the remainder of the clip is withdrawn therefrom. In one embodiment, the support comprises a tubular needle with the distal end being pointed. The needle can be used to penetrate the tissue or material to be joined and to manipulate or approximate tissue or material to be joined before the clip is partially ejected.



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## SURGICAL CONNECTION APPARATUS AND METHODS

### FIELD OF THE INVENTION

5 This invention relates to apparatus and methods for joining structures in surgical procedures such as in laparoscopic procedures.

### BACKGROUND OF THE INVENTION

10 Suturing tissue laparoscopically has always been challenging. Over the past fifteen years or so, there have been many devices developed and marketed to solve this problem. Linear staplers have been the most successful of these devices, but they have limitations. One of the limitations of stapling devices is that one can only place the staples in a pre-determined, confined, straight row. Other stitching type or needle-passing type devices also have been marketed with limited acceptance.

15 Needle management is one concern with these devices. Needle manipulation and knot tying difficulties in confined spaces also have presented concerns. Surgical fasteners or clips, which address suture knot tying problems, are disclosed, for example, in U.S. Patent No. 6,607,541 to Gardiner, et al., U.S. Patent No. 6,514,265 to Ho, et al., U.S. Patent No. 6,613,059 to Schaller, et al. and U.S. Patent No.

20 6,641,593 to Schaller, et al. There remains a need to improve apparatus and methods for joining structures in surgical procedures.

### SUMMARY OF THE INVENTION

25 The present invention involves improvements in surgical connection apparatus and methods. Among the many advantages of the invention is it can be used to readily deliver surgical clips to a surgical site to connect tissue and can eliminate or minimize the need for suturing.

30 According to one embodiment of the invention, surgical connection apparatus comprises a tubular needle having a proximal portion and a distal portion with a pointed distal end, the tubular needle forming a pathway between the proximal and distal portions; a plurality of self-closing clips, each clip being

slidably disposed in the pathway; and a pusher having at least a portion arranged to slidably move in the pathway and push the clips in a distal direction.

According to another embodiment of the invention, surgical connection apparatus comprises a support having a distal portion having a distal end and a proximal portion, the support forming a pathway between the proximal and distal portions; a plurality of self-closing clips, each clip being slidably disposed in the pathway; a pusher having at least a portion arranged to slidably move in the pathway and push the clips in a distal direction; and a stop member extending from said distal portion of the support at a location spaced from the distal end of the support and along the pathway a distance sufficient to allow gathering on the distal portion of the support material to be joined.

According to another embodiment of the invention, surgical connection apparatus comprises a support having a distal portion having a distal end and a proximal portion, the support forming a pathway between the proximal and distal portions; a plurality of self-closing clips, each clip being slidably disposed in the pathway; a pusher having at least a portion arranged to slidably move in the pathway and push the clips in a distal direction; and a stop member extending from the distal portion of the support at a location measured from the distal end of the support and along the pathway a distance less than the length of one of the self-closing clips.

According to another embodiment of the invention, surgical connection apparatus comprises a support having a distal portion having a distal end and a proximal portion, the support forming a pathway between the proximal and distal portions; a plurality of self-closing clips, each clip being slidably disposed in the pathway; and a pusher having at least a portion arranged to slidably move in the pathway and push the clips in a distal direction, the pusher having a first state where it is releasably locked in a first position in the support with one of the clips being in the distal portion of the support and a second state where it is releasably locked in a second position in the support with the one of the clips being partially ejected from the support.

According to another embodiment of the invention, surgical connection apparatus comprising a tubular clip support having a distal portion having a distal end and a proximal portion, the support forming a pathway between the proximal

5 and distal portions, the support having a slot formed therein; a plurality of self-closing clips, each clip being slidably disposed in the pathway; a tubular sleeve surrounding at least a portion of the tubular clip support and having a slot aligned with the slot in the tubular clip support; and a pusher having at least a portion arranged to slidably move in the pathway and push the clips in a distal direction, the pusher extending through the slots.

10 According to another embodiment, a method of connecting tissue comprises penetrating a self-closing clip support through first and second portions of material wherein at least one of the portions comprises tissue; extending a portion of a self-closing clip from the clip support; and simultaneously withdrawing the clip support from said material and allowing the self-closing clip to be discharged therefrom.

15 According to another embodiment, a method of connecting tissue comprises penetrating a self-closing clip support through first and second portions of material wherein at least one of the portions comprises tissue; extending a portion of a self-closing clip, having a memory set closed configuration, from the clip support and allowing the extended portion to move toward its memory set closed configuration; withdrawing the clip support from the material and allowing the self-closing clip to be completely withdrawn from the support and move toward its closed configuration.

20 The above is a brief description of some deficiencies in the prior art and advantages of the present invention. Other features, advantages, and embodiments of the invention will be apparent to those skilled in the art from the following description, accompanying drawings, wherein, for purposes of illustration only, specific forms of the invention are set forth in detail.

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#### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1A is a perspective view of a tissue connecting device in accordance with the present invention;

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FIG. 1B illustrates a surgical clip released from the device of FIG. 1A;

FIG. 1C is a sectional view taken along line 1C-1C in FIG. 1A;

FIG. 2A is a longitudinal sectional view of the device of FIG. 1A;

FIG. 2B depicts a variation of the device illustrated in FIG. 2A;

FIGS. 3A-D illustrate an exemplary use of the device of FIG. 1A where FIG. 3A shows the device positioned in tissue, FIG. 3B depicts partial ejection of a clip from the device of FIG. 3A, FIG. 3C illustrates withdrawal of the device and withdrawal of the clip therefrom, and FIG. 3D illustrates the clip fully released and in a closed configuration.

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#### DETAILED DESCRIPTION OF THE INVENTION

Before the present invention is described, it is to be understood that this invention is not intended to be limited to particular embodiments or examples described, as such may, of course, vary. Further, when referring to the drawings, like numerals indicate like elements.

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The devices, apparatus, and methods described herein generally can be used to surgically connect structures in a patient. They can be used to connect tissue, tissue and prosthetic material, or tissue and graft material. They can be used in endoscopic procedures such as laparoscopic procedures involving connection of tissue within the peritoneal cavity. One example of such procedures is a gastrointestinal bypass procedure. They can be used to connect nontubular or tubular structures. For example, the devices and apparatus described herein can be used to anastomose tubular structures or conduits. The tubular structures can be vascular or nonvascular structures, which can include, but are not limited to, the bile duct, urethra, urinary bladder, intestines, esophagus, stomach, and bowel.

In various embodiments described herein, surgical clips are delivered with a clip support or carrier, which among other things can be used to facilitate approximation of the tissue or material to be joined in addition to carrying the clips.

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Referring to FIGS. 1A and B, one embodiment of surgical connection apparatus in accordance with the principles of the present invention is illustrated and generally designated with reference numeral 100. Surgical connection apparatus or device 100 generally includes outer housing or support 102 and clip support or carrier 104. Clip support 104 forms a pathway for a plurality of clips, e.g., clips 200, to be partially ejected and then withdrawn therefrom. Outer housing or support 102 and clip support 104 can be in the form of tubular members and clip support 104 can be a hypo-needle. Among the many advantages of clip support 104 is it can be sized and/or configured for insertion through endoscopic access ports.

Clip support 104 also can be advantageously sized and/or configured to penetrate the tissue or material to be joined. One of the many advantages of this configuration is that the clip support can be used to penetrate the tissue or material to be joined instead of using the clip carried thereby, which can eliminate the need for introducing a clip with a sharp end and leaving such a clip at the surgical site.

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An actuator or pusher for discharging clips is provided. One example of an actuator or pusher according to the present invention is illustrated in FIGS. 1A and 2A and is generally designated with reference numeral 110. Referring to FIGS. 1A and 2A, actuator 110 moves along slots 106 and 108. Slot 106 is formed in outer housing 102 and extends in a longitudinal direction between the proximal and distal ends thereof. Slot 108 (FIG. 2A) is formed in support 104, extends between the proximal and distal ends thereof, and is aligned with slot 106. Actuator or ejector 110 forms a clip pusher and includes first portion 112, second portion 114, and connecting portion 116. First portion 112 slides or tracks along slot 106 and can be in the form of a button. Second portion 114 tracks inside clip support 104 and forms a pusher rod or member for pushing clips 200 out from apparatus 100. That is, second portion 114 is slidably disposed in the pathway or lumen defined by clip support 104. Second portion 114 can be an elongated member and can be flexible so that it can readily move inside the curved distal end portion 120 of clip support 104. Connecting portion 116 interconnects portions 112 and 114. Although one actuator or ejector configuration is shown, other configurations can be used. According to one variation, the actuator can comprise a pusher rod disposed in the clip support pathway or lumen with its distal end arranged to push clips distally and its proximal end extending proximally and axially from the proximal end of clip support 104 and housing 102.

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Clip support 104 can be shaped so that it can be inserted into the material or tissue with a single motion of the wrist and then withdrawn with a single motion of the wrist. In the illustrative embodiment, clip support 104 has a straight portion 118, shown inside housing 102 in FIG. 2A, and a curved distal end portion 120. The curved portion can improve or simplify manipulation of the distal end portion through materials to be joined as described above and shown in FIGS. 3A-D. Clip support 104 or distal end portion 120 also can have a beveled or sharpened end portion 122 which presents a surface that faces inwardly and which forms a pointed

tip as shown in FIG. 2A. This can enhance the ability of the clip support to penetrate tissue or material to be joined.

Apparatus 100 can be provided with a mechanism to indicate clip position. This mechanism can be used to control the degree or extent of ejection of a respective clip. According to one embodiment, a stopper 124, which can be in the form of a disk, for example, can be secured to the distal portion of clip support 104 to control the degree of penetration of clip support 104. In the illustrative embodiment, the stopper extends from the distal portion of the clip support at a location spaced from the distal end of the clip support and along the clip pathway a distance less than the length of one of the self-closing clips. Preferably this distance will be about one-half the length of one clip and thus ranges from about 1/8 to about 1 inch depending on the application. For example, in laparoscopic procedures for connecting bowel tissue to bowel tissue, this distance will be about 1/4 inch (the clip length being about 1/2 inch). The following is provided to illustrate how the stopper position can facilitate partial clip ejection control or calibration. Specifically, after at least a portion of the clip support forward of the stopper is positioned in the material to be joined, actuator 110 can be moved to partially eject a clip to a position where its distal end is adjacent to the stopper (FIG. 3B). The ejected portion of the clip, which in the illustrative embodiment is about one-half of the clip, moves toward a closed position and forms a hook to grip the material to be joined. With the distal end of the clip adjacent to the stopper, the remaining portion of the clip, which in the illustrative example, is about half of the clip, is then withdrawn from device 100 as device 100 is removed from the attachment site. Accordingly, one of the many advantages of the stopper arrangement is that the relative position of the ejected distal end of a clip and the stopper can be used to indicate the extent of clip ejection and/or to control clip position.

According to a further embodiment, apparatus 100 can be provided with an alternative or additional mechanism to indicate clip position. This mechanism indicates the position of actuator 110 to facilitate control of the degree or extent of ejection of a respective clip. The pusher can have a first state where it is releasably locked in a first position in support 104 with the distal most clip being within the support and a second state where it is releasably locked in a second position in

support 104 with the distal most clip being partially ejected from the support. One example of such a mechanism is shown is shown in FIGS. 1A and C.

Referring to FIGS. 1A and C, the alternative or additional mechanism for indicating clip position comprises a plurality of recesses or depressions 101 formed in outer housing 102, a bore 111a formed in the actuator first portion 112 and a button and spring combination 111b, which is seated in bore 111a. The button can have a spherical shape or other suitable shape as is known in the art. The spring urges the button or post to lockingly engage a respective recess 101, but permits disengagement when sufficient force is applied to actuator 110. Recesses are positioned to facilitate the desired degree of ejection of each clip. For example, if in the initially fully loaded state, the distal most clip is positioned at the distal end of clip support 104 and about one-half of a respective clip 200 is to be ejected, the proximal most recess 101 and recess 101 adjacent thereto can be spaced apart a distance corresponding to about one-half the length of a clip 200 so that movement of actuator 110 from the proximal most recess 101 to the next extends about one-half of the distal most clip out from clip support 104. Since the partially extended clip is then withdrawn from apparatus 100 as described in more detail below, the next clip up for partial ejection will remain spaced from the distal end of clip support 104 by about one-half the length of a clip. Its distal end will be close to where the proximal end of the first partially ejected clip was before the first partially ejected clip was withdrawn and fully removed from apparatus 100. Accordingly, the remaining distance between recesses 101 can correspond to the full length of a clip so that movement of the actuator from one recess 101 to the next recess 101 partially ejects a clip with about one-half the length of the clip extending from clip support 104 and being exposed.

Although one detent mechanism has been described for purposes of illustration, other detent configurations can be used as well as other ejection indicators or control mechanisms. For example, a spring loaded button can be seated in each of the recesses 101 and bore 111a left empty for engagement therewith. According to a further example, indicia can be provided to indicate a predetermined degree of clip ejection when actuator 110 is aligned therewith. Referring to FIG. 2A, exemplary indicia are shown and indicated with reference numeral 103. The outer distal edge of actuator 110 can be aligned with a respective

marking 103 to indicate the degree of clip ejection. The clip position indicators described above can be used alone or in any combination thereof. For example, stopper 124 can be used in combination with the illustrative detent arrangement as shown in FIGS. 1A and C.

5 Further, although clip support 104 is shown with one configuration, others can be used. For example, the distal end portion of clip support 104 can be provided with a corkscrew shape with either a straight or curved center axis. The corkscrew portion can have a one-half or three-quarter turn, for example. When a corkscrew shape and straight center axis is used as shown in FIG. 2B, one can 10 simply rotate outer housing or shaft 102 so that the clip is withdrawn from clip support 104 as the corkscrew shaped distal portion is withdrawn from the materials being joined. Referring to FIG. 2B, the corkscrew variation of the clip support is 15 designated with reference numeral 104'. Other than the corkscrew configuration at the distal portion of clip support 104' and the hypo-needle straight portion extending a small distance beyond stopper 124, clip support 104' as shown in FIG. 2B is the same as clip support 104.

As described above, clips 200 can be disposed inside clip support 104 as 20 shown in FIG. 2A. The clips are aligned serially and, thus, can be ejected or applied consecutively without the need to withdraw the device or clip support 104 from the endoscopic or access port to reload. The number of clips which can be 25 housed in clip support 104 is a function of clip size and the length of the clip support. Clip support or hypo-needle 104 constrains the clips in an open position and provides a means of tissue penetration. In operation, clip support 104 is penetrated through the target material. It can have a pointed or sharpened distal end as described above to enhance its ability to readily penetrate tissue or material to be joined. As will be described in more detail below, each clip is partially ejected from 30 the device via actuator 110 after which device 100 is withdrawn, thus allowing closure of the clip. Using the clip support to penetrate tissue can eliminate the need to penetrate tissue with the clip and the need to use a clip having one or more sharp ends. Accordingly, clips 200 can have two non-pointed or rounded ends. Although ball shaped or spherically shaped ends are shown in the illustrative embodiment, other shapes providing non-pointed ends can be used as well.

5 Returning to FIG. 1B, one suitable clip configuration is shown. In the illustrative embodiment, surgical clip 200 includes ball shaped proximal and distal ends and a loop shaped memory set shape or configuration. Although clip 200 is shown with an overlapping loop closed configuration, it can be non-overlapping or otherwise shaped differently than that shown when in its memory set closed shape. Clips 200 are self-closing clips in that they return toward their memory set configuration after being released from a deformed configuration.

10 Self-closing clips 200 can be made from nitinol wire and provided with the desired memory set configuration to exhibit pseudoelastic (superelastic) behavior. In other words, at least a portion of the shape memory alloy is converted from its austenitic phase to its martensitic phase when the wire is in its deformed configuration. As the stress is removed, the material undergoes a martensitic to austenitic conversion and springs back to its original undeformed configuration.

15 The shape memory alloy can be selected with a transformation temperature suitable for use with a stopped heart condition where cold cardioplegia has been injected for temporary paralysis of the heart tissue (e.g., temperatures as low as 8-10 degrees Celsius).

20 The cross-sectional diameter of the wire and length of the wire will vary depending on the specific application. The diameter of the wire may be, for example, between 0.004 and 0.025 inch and the diameter of the wire loop may range from about 0.020 to about 0.500 inch. The wire may be formed in a loop shape by first wrapping the wire onto a mandrel and heat treating the wire at approximately 400-500 degrees Celsius for approximately 5 to 30 minutes. The wire is then air quenched at room temperature.

25 It is to be understood that the shape memory alloy may also be heat activated, or a combination of heat activation and pseudoelastic properties may be used as is well known by those skilled in the art.

30 Clip support 104 can be formed from a hypo-needle, which can be made from a piece of surgical grade stainless steel tubing, one end of which can be beveled and sharpened. Beveled and sharpened hypo-needles are common in the industry. One end portion of the hypo-needle can be shaped to have a curvature as described above. The outer housing 102 forms a shaft or handle for clip support 104 and can be machined metal, injection-molded plastic, or extruded plastic.

Housing 102 also can be formed as a single unitary structure or a combination of joined parts.

5 The following describes an exemplary use of apparatus 100 and is not intended to limit the invention. This example is illustrative of connecting tissue to tissue within the peritoneal cavity. It should be understood that the device can be used to connect other tissue or materials as described above.

10 In accordance with the example, a distal end portion of clip support 104 of apparatus 100 is inserted through a laparoscopic port where the distal end of clip support or hypo-needle 104 is manipulated to penetrate or pierce a first portion "A" of target tissue and then to penetrate or pierce another portion "B" of the same or different target tissue, which prior to the procedure may be spaced from one another. Penetration through portions A and B can be accomplished with a single twist or motion of the wrist. Observation can be accomplished through placement of an endoscopic camera in another port as is known in the art. The clip support or hypo-needle 104 is positioned so that it completely penetrates through both portions of tissue and the stopper is in contact with the first portion as shown in FIG. 3A. In this position only the sharp tip of the hypo-needle should be visibly protruding from the second portion of tissue of tissue (FIG. 3A). Clip support 104 can effect or facilitate tissue approximation as it is passed through both tissue portions and manipulated. Stopper 124 also can be positioned to facilitate tissue manipulation and/or approximation as it can be used to push one tissue portion against the other. Accordingly, stopper 124 can be positioned so that it extends from the distal portion of clip support 104 at a location spaced from the distal end of clip support 124 and along the clip pathway defined by the support (e.g., the clip support lumen when a tubular support is used) a distance sufficient to allow gathering on the clip support material to be joined. The distance typically will range from about 1/8 inch to about 1 inch depending on the application.

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30 Referring to FIG. 3B, actuator 110 is moved distally or forward so that a distal end portion of the distal most clip in the hypo-needle is extended therefrom and its distal end just covers the seam between the two portions of tissue (FIG. 3B). In this example, the distal end of the clip is adjacent to stopper 124 indicating that about one-half the clip has been ejected. Apparatus 100 can alternatively or in addition include a further mechanism to indicate the position of a respective clip

(e.g., partial ejection such as ejection of one-half of the clip) as described above in connection with FIGS. 1A and C.

The hypo-needle is then withdrawn from the tissue in the opposite direction from its entry as shown in FIG. 3C. The surgeon can accomplish this with a slight 5 twist or single motion of the wrist or a slight reverse-pull motion. As the hypo-needle is withdrawn, the proximal portion of the clip, which was held inside the hypo-needle by friction, is withdrawn and remains in the tissue. After the clip is fully withdrawn from the hypo-needle, it moves toward its shape memory set closed 10 configuration (FIG. 3D) and holds the tissue together. Clip support 104 of apparatus 100, which was loaded with a plurality of clips 200, can then be manipulated to reposition the clip support along the tissue portions or seam to deploy another clip. This can be done without removing the distal end of clip support 104 from the endoscopic port. After the procedure is completed, the clip support or hypo-needle is retracted. The foregoing procedure involves or uses a 15 single needle, hypo-needle 104, and thus can eliminate or minimize needle management concerns.

Any feature or combination of features of any one embodiment described herein can be combined with any other feature or combination of features of one or more of the other embodiments.

Variations and modifications of the devices and methods disclosed herein 20 will be readily apparent to persons skilled in the art. As such, it should be understood that the foregoing detailed description and the accompanying 25 illustrations, are made for purposes of clarity and understanding, and are not intended to limit the scope of the invention, which is defined by the claims appended hereto.

## WHAT IS CLAIMED IS:

1. Surgical connection apparatus comprising:
  - 5 a tubular needle having a proximal portion and a distal portion with a pointed distal end, said tubular needle forming a pathway between said proximal and distal portions;
  - 10 a plurality of self-closing clips, each clip being slidably disposed in said pathway; and
  - 15 a pusher having a portion arranged to slidably move in said pathway and push said clips in a distal direction.
2. The apparatus of claim 1 wherein each clip has a first end and a second end, at least one of said ends of each clip is rounded.
3. The apparatus of claim 2 wherein both of said ends of each clip are rounded.
4. The apparatus of claim 1 further including a stop member extending from said distal portion of said tubular needle at a location spaced from the distal end of said tubular needle and along said pathway a predetermined distance less than the length of one of said self-closing clips.
5. The apparatus of claim 4 wherein said distance ranges from about 1/8 inch to about 1 inch.
6. The apparatus of claim 1 further including a stop member extending from said distal portion of said tubular needle at a location spaced from the distal end of said tubular needle and along said pathway a distance sufficient to allow gathering on said tubular needle material to be joined.
7. The apparatus of claim 6 wherein said distance ranges from about 1/8 inch to about 1 inch.
8. The apparatus of claim 1 wherein said tubular needle distal portion is curved.
9. The apparatus of claim 1 wherein said tubular needle distal portion has a spiral portion.
- 30 10. The apparatus of claim 1 wherein said tubular needle comprises a hypo-needle.

11. The apparatus of claim 10 wherein said hypo-needle has a slot formed therein, said slot extending toward said distal end of said tubular needle and said pusher having a portion extending through said slot.  
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12. The apparatus of claim 1 wherein said tubular needle has a slot formed therein, said slot extending toward said distal end of said tubular needle and said pusher having a portion extending through said slot.  
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13. The apparatus of claim 1 wherein each clip has a memory set closed configuration, when said clips are disposed in said tubular needle, said tubular needle biases said clips away from said closed configuration, and when said clips are released from said tubular needle, said clips move toward their memory set closed configuration.  
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14. The apparatus of claim 13 wherein said clips have a loop shaped memory set closed configuration.  
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15. The apparatus of claim 1 wherein said clips have a loop shaped memory set closed configuration.  
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16. Surgical connection apparatus comprising:
  - a support having a distal portion having a distal end and a proximal portion, said support forming a pathway between said proximal and distal portions;
  - a plurality of self-closing clips, each clip being slidably disposed in said pathway;
  - a pusher having a portion arranged to slidably move in said pathway and push said clips in a distal direction; and
  - a stop member extending from said distal portion of said support at a location spaced from the distal end of said support and along said pathway a distance sufficient to allow gathering on said distal portion of said support material to be joined.  
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17. The apparatus of claim 16 wherein said support comprises a tubular member and said self-closing clips are slidably disposed in said tubular member and serially arranged.
18. The apparatus of claim 16 wherein said support distal portion is curved.
19. The apparatus of claim 16 wherein said support distal portion has a spiral portion.
20. The apparatus of claim 16 wherein said support member comprises a tubular member and said distal end is pointed.

21. The apparatus of claim 20 wherein said tubular member comprises a hypo-needle.
22. The apparatus of claim 21 wherein said hypo-needle has a slot formed therein, said slot extending toward said distal end of said support and said pusher having a portion extending through said slot.
- 5 23. The apparatus of claim 16 wherein said support comprises a tubular member, which forms at least a portion of said pathway, each clip has a memory set closed configuration, when said clips are disposed in said tubular member, said tubular member biases said clips away from said closed configuration, and when said clips are released from said tubular member, said clips move toward their memory set closed configuration.
- 10 24. The apparatus of claim 16 wherein said clips have a loop shaped memory set closed configuration.
25. The apparatus of claim 24 wherein said support comprises a tubular member and said self-closing clips are slidably disposed in said tubular member and serially arranged.
- 15 26. The apparatus of claim 16 wherein each clip has a first end and a second end, at least one of said ends of each clip is rounded.
27. The apparatus of claim 26 wherein both of said ends of each clip are rounded.
28. The apparatus of claim 16 wherein said distance ranges from about 1/8 inch to about 1 inch.
- 20 29. Surgical connection apparatus comprising:
  - a support having a distal portion having a distal end and a proximal portion, said support forming a pathway between said proximal and distal portions;
  - a plurality of self-closing clips, each clip being slidably disposed in said pathway;
  - 25 a pusher having a portion arranged to slidably move in said pathway and push said clips in a distal direction; and
  - a stop member extending from said distal portion of said support at a location spaced from the distal end of said support and along said pathway a predetermined distance less than the length of one of said self-closing clips.
- 30 30. The apparatus of claim 29 wherein said support comprises a tubular member and said self-closing clips are slidably disposed in said tubular member and serially arranged.

31. The apparatus of claim 29 wherein said support distal portion is curved.
32. The apparatus of claim 29 wherein said support distal portion has a spiral portion.
33. The apparatus of claim 29 wherein said support comprises a tubular member and said distal end is pointed.  
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34. The apparatus of claim 33 wherein said tubular member comprises a hypo-needle.
35. The apparatus of claim 34 wherein said hypo-needle has a slot formed therein, said slot extending toward said distal end of said support and said pusher having a portion extending through said slot.  
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36. The apparatus of claim 29 wherein said support comprises a tubular member, which forms at least a portion of said pathway, each clip has a memory set closed configuration, when said clips are disposed in said tubular member said tubular member biases said clips away from said closed configuration, and when said clips are released from said tubular member said clips move toward their memory set closed configuration.  
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37. The apparatus of claim 29 wherein said clips have a loop shaped memory set closed configuration.
38. The apparatus of claim 37 wherein said support comprises a tubular member and said self-closing clips are slidably disposed in said tubular member and serially arranged.  
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39. The apparatus of claim 29 wherein each clip has a first end and a second end, at least one of said ends of each clip is rounded.
40. The apparatus of claim 39 wherein both of said ends of each clip are rounded.  
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41. The apparatus of claim 29 wherein said distance ranges from about 1/8 inch to about 1 inch.
42. Surgical connection apparatus comprising:  
30  
a support having a distal portion having a distal end and a proximal portion, said support forming a pathway between said proximal and distal portions;  
a plurality of self-closing clips, each clip being slidably disposed in said pathway; and  
a pusher having a portion arranged to slidably move in said pathway and push said clips in a distal direction, said pusher having a first state where it is releasably

locked in a first position in said support with one of said clips being in the distal portion of said support and a second state where it is releasably locked in a second position in said support with said one of said clips being partially ejected from said support.

43. The apparatus of claim 42 wherein said support comprises a tubular member and said self-closing clips are slidably disposed in said tubular member.
44. The apparatus of claim 43 wherein said clips are serially arranged.
45. The apparatus of claim 42 wherein said support distal portion is curved.
46. The apparatus of claim 42 wherein said support distal portion has a spiral portion.
47. The apparatus of claim 42 wherein said support comprises a tubular member and said distal end is pointed.
48. The apparatus of claim 47 wherein said tubular member comprises a hypo-needle.
49. The apparatus of claim 48 wherein said hypo-needle has a slot formed therein, said slot extending toward said distal end of said support and said pusher extending through said slot.
50. The apparatus of claim 49 including a second tubular member surrounding a portion of said support and having a slot formed therein and aligned with said slot in said hypo-needle, said pusher extending through both slots.
51. The apparatus of claim 50 wherein said second tubular member has a plurality of recesses and said pusher has a recess, further including a spring loaded button disposed in said pusher recess and said pusher being movable to align said spring loaded button with said second tubular member recesses.
52. The apparatus of claim 42 wherein each clip has a memory set closed configuration, when said clips are disposed in said tubular member said tubular member biases said clips away from said closed configuration, and when said clips are released from said tubular member said clips move toward their memory set closed configuration.
53. The apparatus of claim 42 wherein said clips have a loop shaped memory set closed configuration.
54. The apparatus of claim 53 wherein said support comprises a tubular member and said self-closing clips are slidably disposed in said tubular member.

55. The apparatus of claim 42 wherein each clip has a first end and a second end, at least one of said ends of each clip is rounded.

56. The apparatus of claim 55 wherein both of said ends of each clip are rounded.

57. The apparatus of claim 42 further including a stop member extending from said distal portion of said support at a location spaced from the distal end of said support and along said pathway a distance less than the length of one of said self-closing clips.

58. The apparatus of claim 57 wherein said distance ranges from about 1/8 inch to about 1 inch.

10 59. The apparatus of claim 42 further including a stop member extending from said distal portion of said support at a location spaced from the distal end of said support and along said pathway a distance sufficient to allow gathering on said tubular needle material to be joined.

15 60. The apparatus of claim 59 wherein said distance ranges from about 1/8 inch to about 1 inch.

61. Surgical connection apparatus comprising:  
a tubular clip support having a distal portion having a distal end and a proximal portion, said support forming a pathway between said proximal and distal portions, said support having a slot formed therein;

20 62. The apparatus of claim 61 further including a plurality of self-closing clips, each clip being slidably disposed in said pathway;  
a tubular sleeve surrounding at least a portion of said tubular clip support and having a slot aligned with said slot in said tubular clip support; and  
a pusher arranged to slidably move in said pathway and push said clips in a distal direction, said pusher extending through said slots.

25 63. The apparatus of claim 62 wherein said distance ranges from about 1/8 inch to about 1 inch.

30 64. The apparatus of claim 61 further including a stop member extending from said

distal portion of said support at a location spaced from the distal end of said support and along said pathway a distance sufficient to allow gathering on said tubular needle material to be joined.

5        65.      The apparatus of claim 64 wherein said distance ranges from about 1/8 inch to about 1 inch.

10        66.      The apparatus of claim 61 wherein said pusher has a first state where it is releasably locked in a first position in said support with one of said clips being within the distal portion of said support and a second state where it is releasably locked in a second position in said support with said one of said clips being partially ejected from said support.

15        67.      The apparatus of claim 66 wherein said tubular sleeve has a plurality of recesses and said pusher has a recess, further including a spring loaded button being disposed in said pusher recess and said pusher being movable to align said spring loaded button with said second tubular member recesses.

20        68.      The apparatus of claim 61 wherein said clips are serially aligned.

69.      The apparatus of claim 61 wherein each clip has a first end and a second end, at least one of said ends of each clip is rounded.

70.      The apparatus of claim 69 wherein both of said ends of each clip are rounded.

25        71.      The apparatus of any one of claims 61-70 wherein said clip support comprises a tubular member and said distal end is pointed.

72.      The apparatus of claim 71 wherein said clip support comprises a hypo-needle.

73.      A method of connecting tissue comprising:  
              penetrating a self-closing clip support through first and second portions of material  
              wherein at least one of said portions comprises tissue;  
              extending a portion of a self-closing clip from said clip support; and  
              simultaneously withdrawing said clip support from said material and allowing said self-closing clip to be discharged therefrom.

30        74.      A method of connecting tissue comprising:  
              penetrating a self-closing clip support through first and second portions of material  
              wherein at least one of said portions comprises tissue;  
              extending a portion of a self-closing clip, having a memory set closed

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configuration, from said clip support and allowing the extended portion to move toward its memory set closed configuration;

5 withdrawing said clip support from said material and allowing said self-closing clip to be completely withdrawn from said support and move toward its closed configuration.

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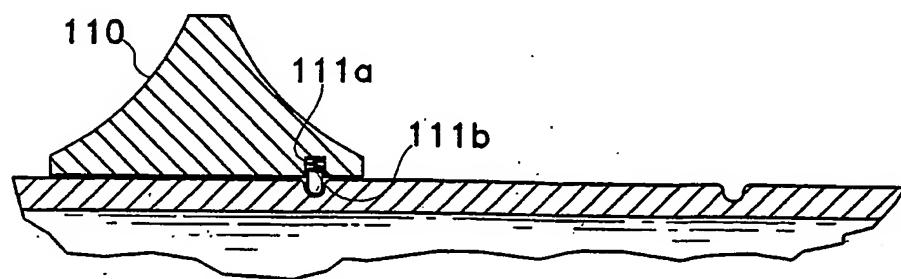


Fig. 1C

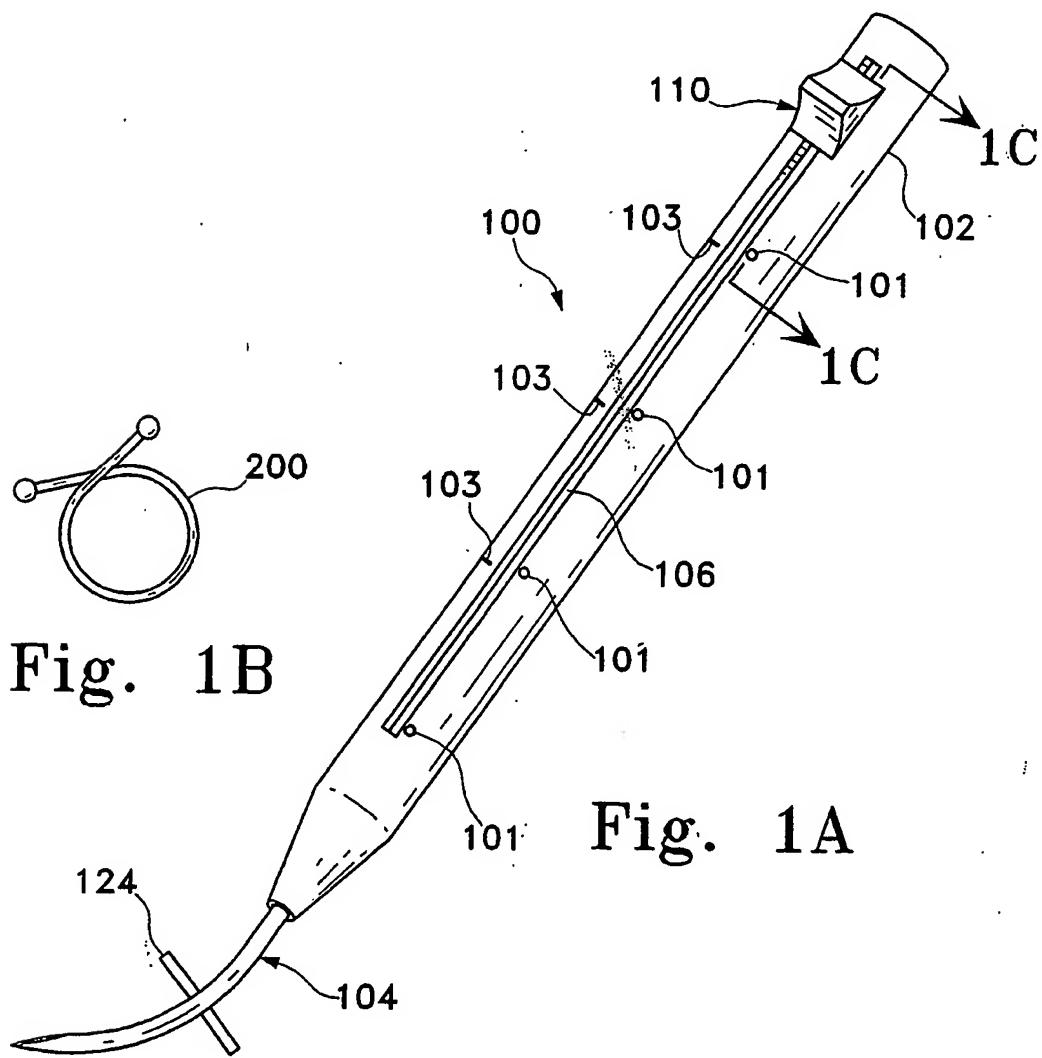


Fig. 1B

Fig. 1A

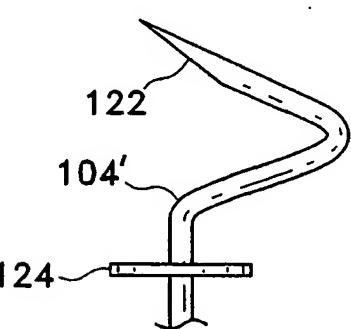
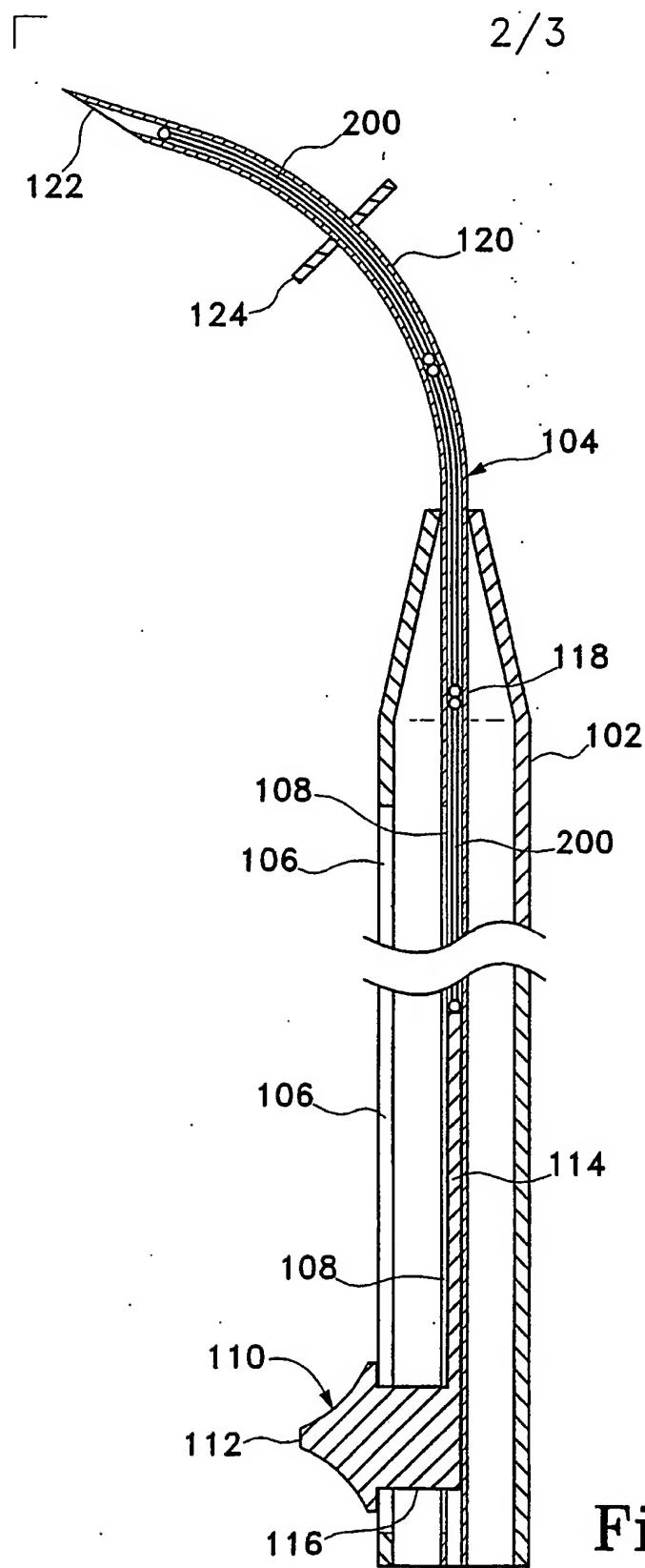


Fig. 2A

Fig. 2B

□

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Fig. 3A

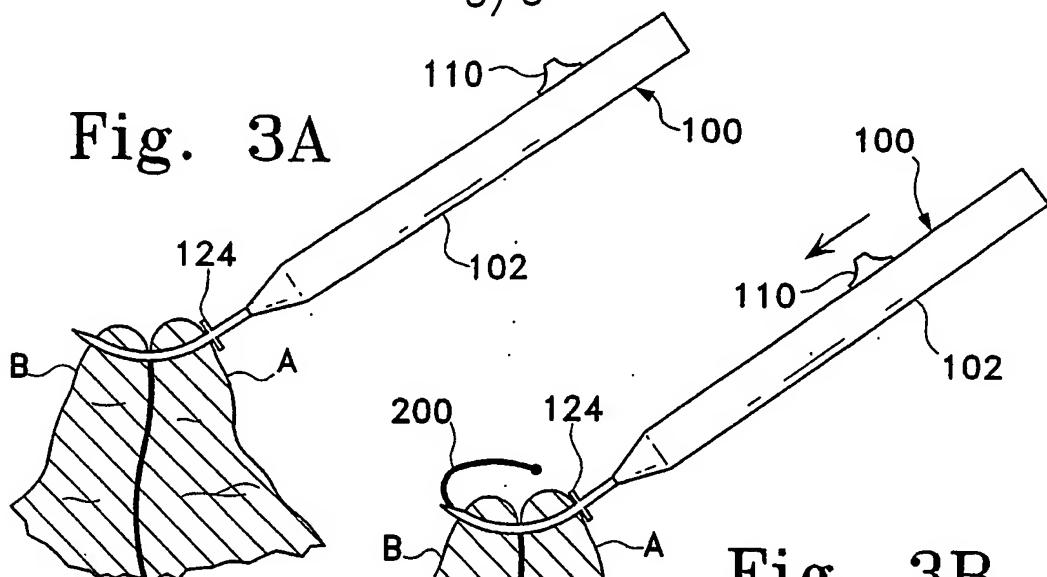


Fig. 3B



Fig. 3C

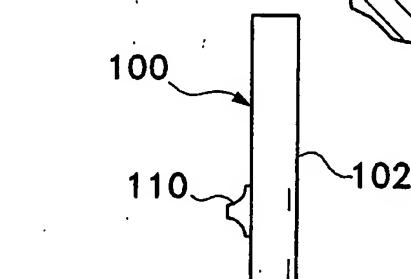
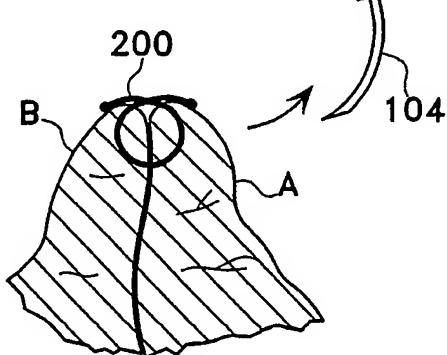
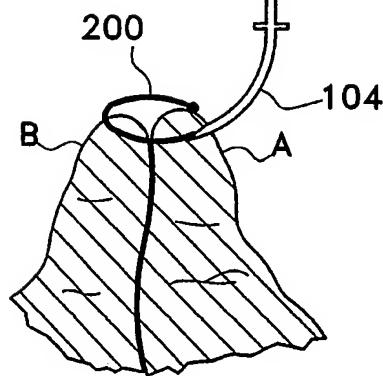
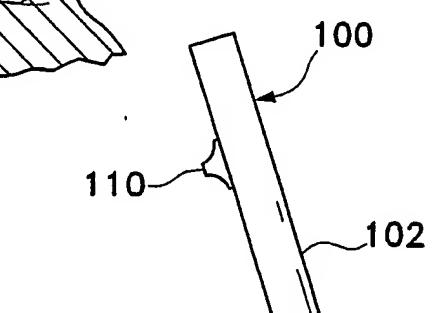


Fig. 3D



# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US2004/041211

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 A61B17/12 A61B17/08

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)  
IPC 7 A61B A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6 350 269 B1 (SHIPP JOHN I ET AL) 26 February 2002 (2002-02-26)	1-3, 6-8, 13-18, 20, 21, 23-28, 42-45, 47-56, 59, 60 4, 5, 9-12, 19, 22, 29-41, 46, 57, 58, 61-72
A	abstract; figures  column 3, line 30 - column 4, line 16 column 5, line 60 - column 8, line 51 column 9, line 16 - column 12, line 15 ----- -/-	

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

• Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

3 May 2005

Date of mailing of the International search report

11/05/2005

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl  
Fax: (+31-70) 340-3016

Authorized officer

Lager, J

## INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US2004/041211

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 409 569 A (UNITED STATES SURGICAL CORPORATION) 23 January 1991 (1991-01-23) abstract; figures	1-3, 16, 29, 42, 61
A	column 1, lines 6-12 column 2, line 14 - column 3, line 51 column 4, line 23 - column 5, line 3 column 5, lines 34-47	4-15, 17-28, 30-41, 43-60, 62-72
A	US 2002/151916 A1 (MURAMATSU JUNICHI ET AL) 17 October 2002 (2002-10-17) abstract; figures paragraph '0012! paragraph '0014! paragraph '0063! - paragraph '0069! paragraph '0074! paragraph '0077! paragraph '0172! - paragraph '0205!	1-72
A	US 6 607 542 B1 (WILD ANDREW MICHAEL) 19 August 2003 (2003-08-19) abstract; figures	1-72
A	US 5 242 456 A (NASH ET AL) 7 September 1993 (1993-09-07) abstract; figures	1-72
A	US 5 356 424 A (BUZERAK ET AL) 18 October 1994 (1994-10-18) abstract; figures	1-72
A	US 2002/165561 A1 (AINSWORTH STEPHEN ET AL) 7 November 2002 (2002-11-07) abstract; figures	1-72

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US2004/041211

## Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1.  Claims Nos.: 73-74 because they relate to subject matter not required to be searched by this Authority, namely:  
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery
2.  Claims Nos.: because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3.  Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1.  As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2.  As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3.  As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4.  No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

The additional search fees were accompanied by the applicant's protest.  
 No protest accompanied the payment of additional search fees.

**INTERNATIONAL SEARCH REPORT**

Information on patent family members

International Application No

PCT/US2004/041211

Patent document cited in search report	Publication date		Patent family member(s)	Publication date
US 6350269	B1	26-02-2002	US 2002082615 A1 US 2002082618 A1 US 2004106936 A1	27-06-2002 27-06-2002 03-06-2004
EP 0409569	A	23-01-1991	US 5100420 A US 5084057 A AU 632348 B2 AU 5912690 A CA 2021362 A1 DE 9018151 U1 DE 69029823 D1 DE 69029823 T2 DE 69033507 D1 DE 69033507 T2 DE 69033727 D1 DE 69033727 T2 DE 409569 T1 EP 0409569 A1 EP 0738499 A2 EP 0738500 A2 JP 3136641 A US 5383881 A US 5645551 A US 5527318 A US 5423835 A US 5382254 A	31-03-1992 28-01-1992 24-12-1992 24-01-1991 19-01-1991 07-11-1996 13-03-1997 12-06-1997 18-05-2000 14-09-2000 23-05-2001 13-09-2001 25-11-1993 23-01-1991 23-10-1996 23-10-1996 11-06-1991 24-01-1995 08-07-1997 18-06-1996 13-06-1995 17-01-1995
US 2002151916	A1	17-10-2002	JP 2002301082 A DE 10203956 A1	15-10-2002 26-09-2002
US 6607542	B1	19-08-2003	AU 1670600 A EP 1139885 A2 WO 0035355 A2	03-07-2000 10-10-2001 22-06-2000
US 5242456	A	07-09-1993	AU 2384192 A CA 2122935 A1 WO 9309721 A1	15-06-1993 27-05-1993 27-05-1993
US 5356424	A	18-10-1994	NONE	
US 2002165561	A1	07-11-2002	US 2002173803 A1 WO 02087425 A2	21-11-2002 07-11-2002